Enabling Artificial Intelligence & Machine Learning through Public-Private Partnerships

ANSI Brainstorming Session

Welcome & Objectives

Event Logistics

- **Recording**
  - ANSI is recording this session for internal purposes only. No references to specific individuals will be made in the final report.
- **Internet Access**
  - Network: AAMI Guest
  - Password: duty have gain
- **Facilities (Thank you AAMI!)**
  - Emergency Exit
  - Food, Beverage, and Trash
  - Restrooms
  - Private Huddle/Call rooms
- **In-Room Participation**
  - Raise your hand to speak
  - Always use a mic
  - Leave table mic muted when not speaking
  - Name / Company – Share this each time you speak
- **Online Participation**
  - Participation through Slido
  - Change your name on Zoom (First / Last Name)
  - Contact "ANSI Zoom Support 1 / 2" for connectivity assistance

Background

- ANSI is gathering input to inform the NIST implementation plan for the USG NSS CETs
  - USG National Standards Strategy for CETs issued May 2023
  - Draft Roadmap for USG National Standards Strategy for CET (comment period closed July 12th)

- ANSI coordinating private-sector to:
  - Identify existing and past public-private partnerships (PPPs)
  - Learn approaches, best practices and lessons learned
  - Learn different mechanisms for how PPPs convene stakeholders
  - Discuss what role PPPs can play to support CETs
  - Determine if there are stages of where a PPP is appropriate based on maturity of standards development

- Effort is supported through a cooperative agreement with NIST

Session Objectives

- Explore the use of public-private partnerships (PPPs) to share information and identify priority standards development activities

- Today's discussion-based session will focus on AI in healthcare and manufacturing
  - opportunities and challenges associated with AI/ML in healthcare and manufacturing;
  - how PPPs could enable / accelerate AI/ML general and application-specific standards development and technology integration into the marketplace;
  - the relationship between standards readiness and relevant types of PPPs.

Review Session Agenda

SESSION 1: TECHNOLOGY CONVERGENCE AND STANDARDS READINESS BRIEFINGS	
9:30 – 10:10 am	**Presentations**
SESSION 2: CHALLENGES, OPPORTUNITIES, AND STANDARDS READINESS DISCUSSION	
10:10 – 10:25 am	**Discussion Preparation: Challenges, Opportunities, and Standards Readiness**
10:25 – 10:40 am	**Networking Break**
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3:50 – 4:30 pm	**Future State of Information Sharing Discussion**
4:30 – 5:00 pm	**Key Takeaways & Closing Remarks**

Slido Guidance for All Attendees

How to engage in discussion?

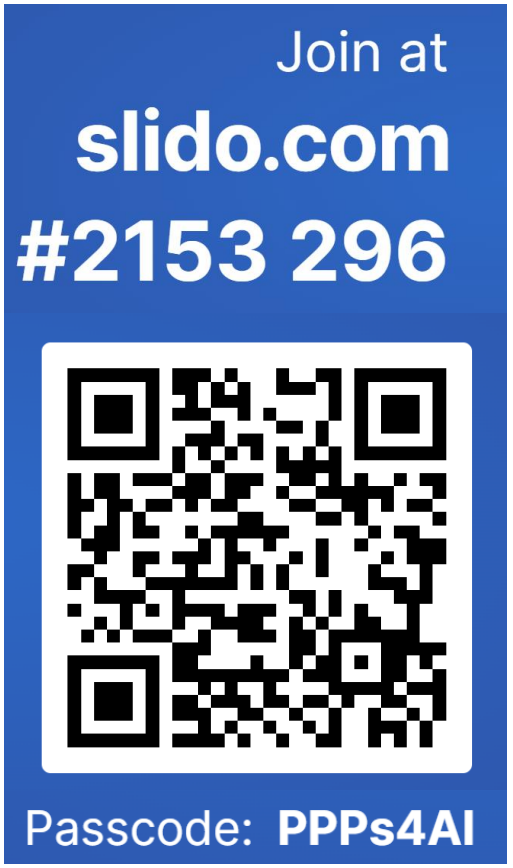
- ALL ATTENDEES: Polls / surveys for targeted questions
- ONLINE ATTENDEES: Q&A for Discussion
- IN PERSON: Raise your hand (primary), contribute to Slido Q&A

How to I find the Slido?

- QR Code found on most discussion slides
- Event link is on the Agenda in my Friday, 7/12 Email (11am)
- On the AI / ML event webpage

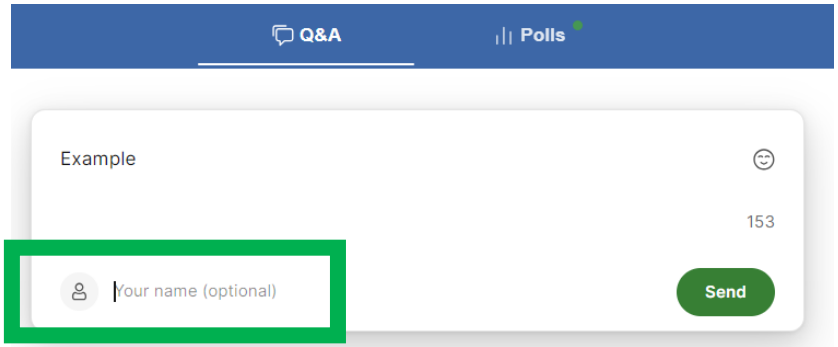
What can everyone see?

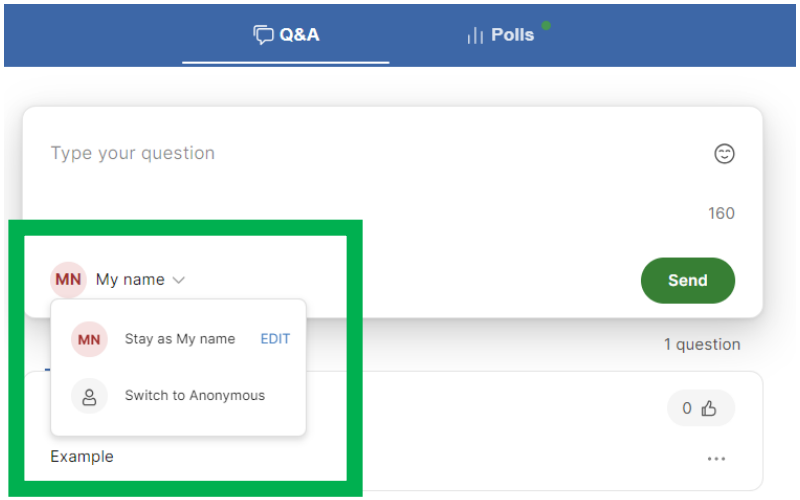
- First and Last Name (Company) OR Anonymous
- Have something more sensitive in nature to share? Participants can change this setting based on each response



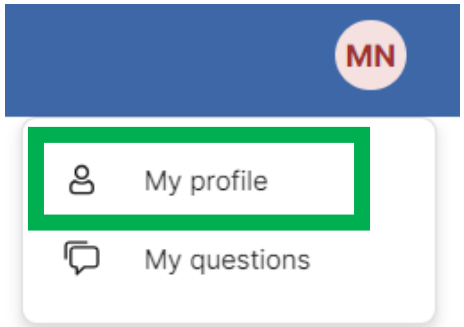
Slido: Your Name OR Anonymous

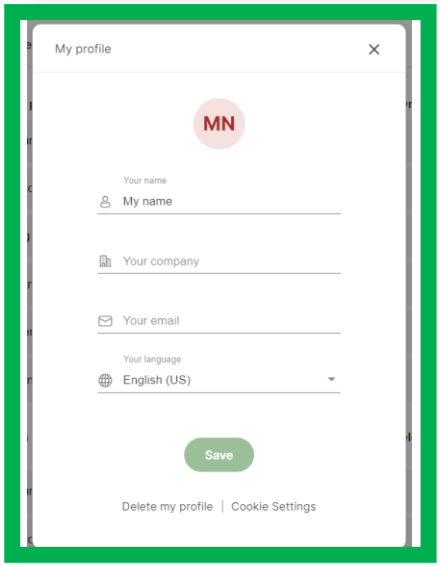
On Q&A





On Slido Profile





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Session 1: Technology Convergence & Standards Readiness Briefings

Technology conversion points

- Laura Lindsay, Microsoft

Standards Readiness Considerations

- Clare Allocca, NIST

Standards Readiness Phases

- Christine Bernat, ANSI

Technology conversion points

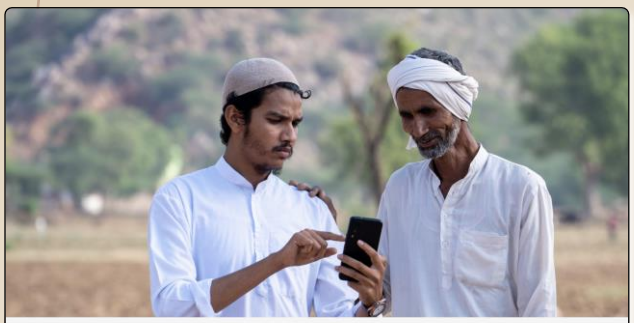
Laura Lindsay
National Standards Officer
Microsoft

TECHNOLOGY CONVERGENCE AND STANDARDS READINESS

TECHNOLOGY CONVERSION POINTS

LAURA LINDSAY
STANDARDS STRATEGIST
MICROSOFT

The promises of AI

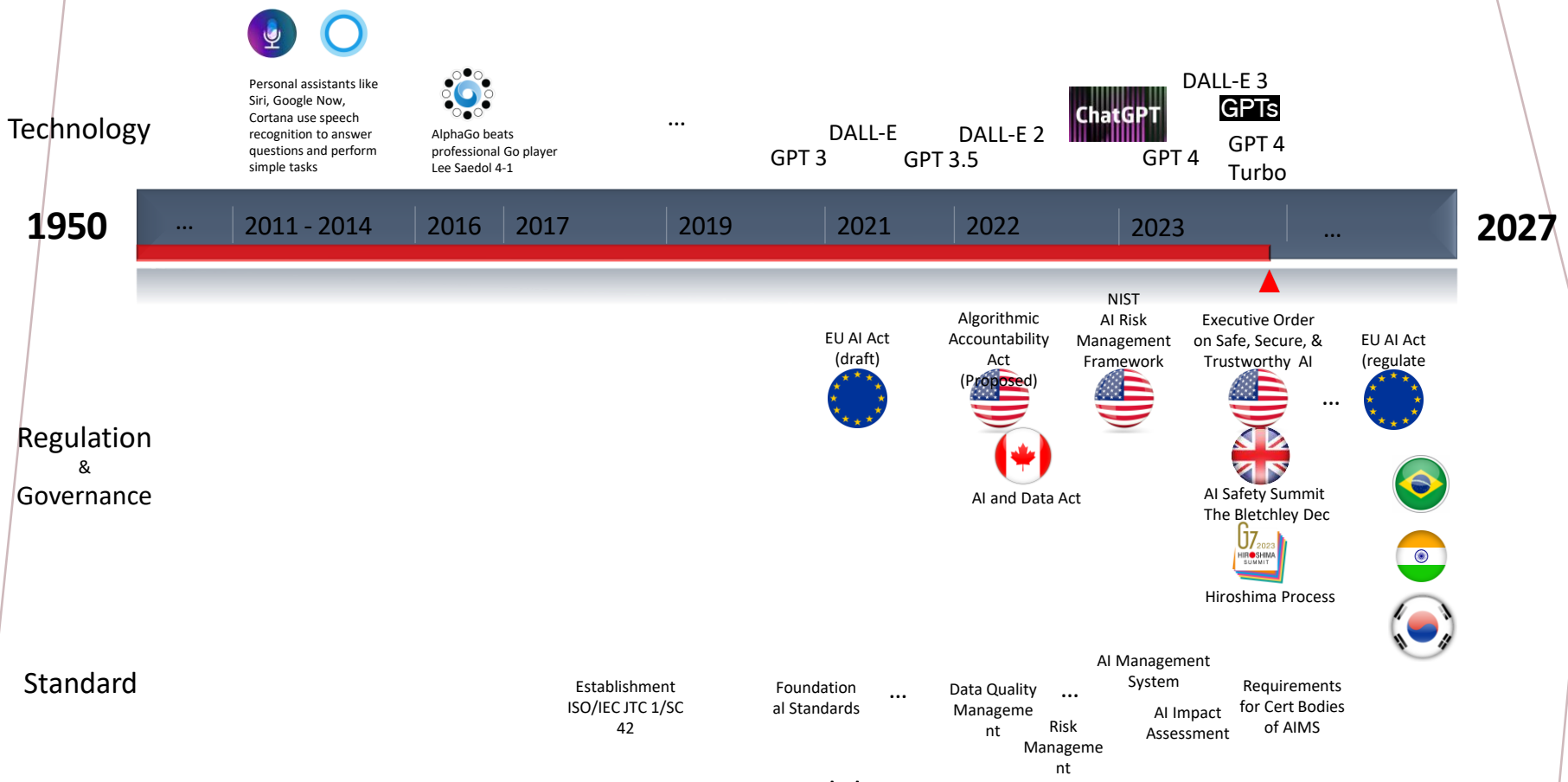


With help from next-generation AI, Indian villagers gain easier access to government services

Taiwan brings in generative AI to help students learn English

New Taipei City, TAIWAN – Teachers often report that students learning English tend to read and write better than they speak, as shyness and a lack of practice can hinder the ability to converse. Now, a chatbot funded by Taiwan's Ministry of Education and running on next-generation large language models offers a way for K-12 students to get that practice, and in a more engaging way than was previously possible.

Hack For Public Good '23 Pair: AI writing assistant for public officials in Singapore



Responsible AI

WHY DO WE NEED AI STANDARDS

- Establishes global “rules of the road” based on input from civil society, academia, government and industry
- Enables global coherence between different regulatory regimes which is essential for industry
- Enables trust in organizations
- Enables responsible development and use of trustworthy AI systems
- Accountability and transparency
- Improve market adoption of technologies
- Support regulatory outcomes

AI STANDARDS NEEDED

Terminology and concepts

Risk management

Governance implications of the use of AI

Data quality management

Quality models for AI systems

AI Management system

AI system impact assessment

Trustworthiness

- Unwanted bias
- Transparency
- Explainability
- Controllability
- Human oversight

Testing of AI systems

Best practices

(data capture, privacy, transparency, confidentiality, etc.)

Application or Sector specific AI guidance

WHERE ARE AI STANDARDS AT

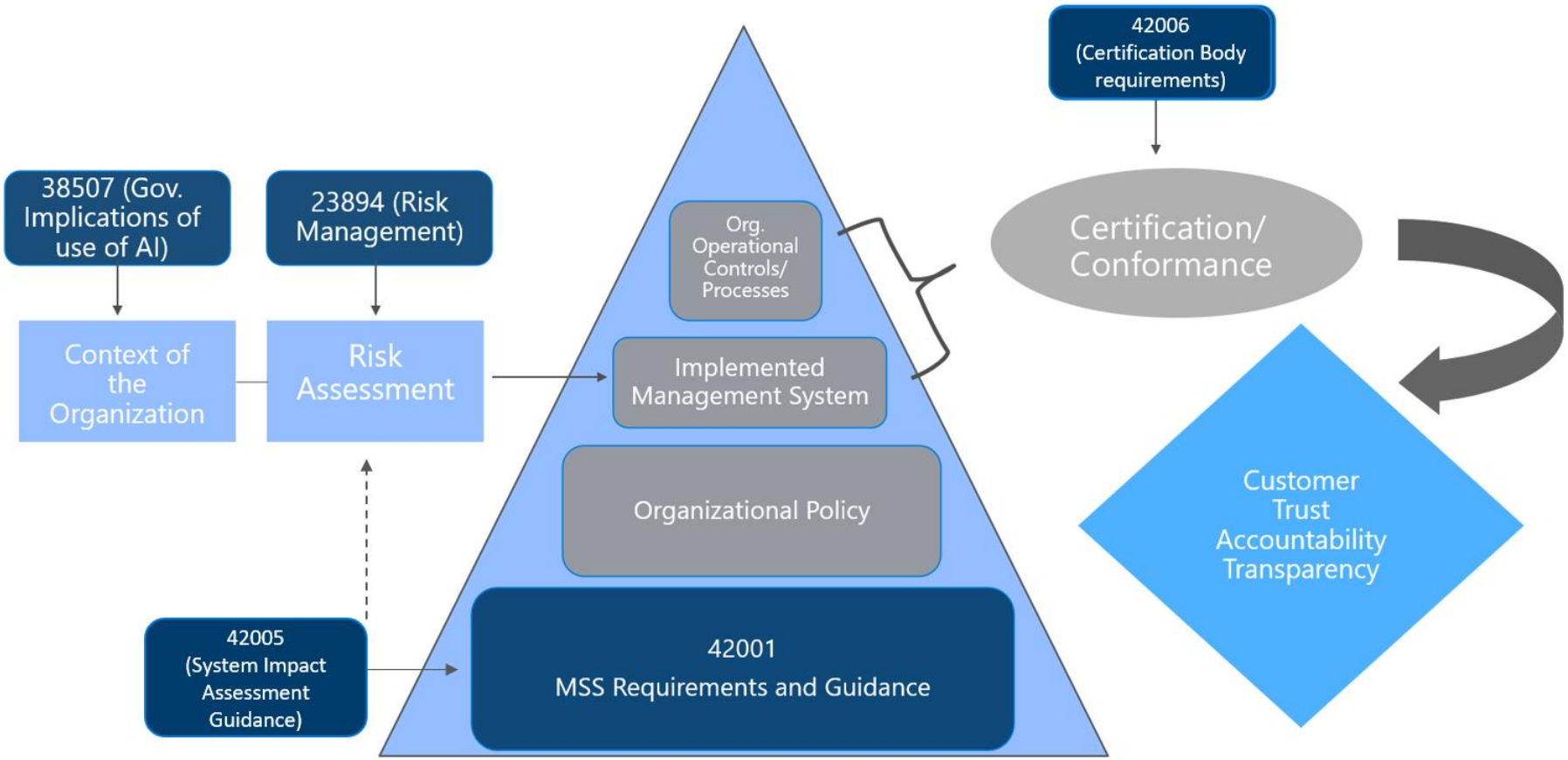
- ISO/IEC have issued over 20 standards on terminology, risk framework, data management, AI Management Systems, and many more.
- ISO/IEC 42001 established the framework for quality models for AI systems with consistent terminology for specifying, measuring and evaluating system quality.
- ISO/IEC expects to publish ISO/IEC 42005 in 6-12 months. This will provide international standards for AI tailored to different domains and applications.

ISO/IEC 42001 AI MANAGEMENT SYSTEM

AIMS structure

Management clauses	Reference controls categories	AI related organizational objectives, risk sources and use of AIMS across sectors
• Context of the organization • Leadership • Planning • Support • Operation • Performance Evaluation • Improvement	• Policies related to AI • Internal organization • Resources for AI systems • Assessing impacts of AI systems • AI system life cycle • Data for AI systems • Information for interested parties of AI systems • Use of AI systems • Third-party and customer relationships	• Organizational objectives • Risk sources • Integration of AIMS with other management system standards

SUPPORTING STANDARDS IN THE FOUNDATIONAL AI ECOSYSTEM



NEXT STEPS FOR AI STANDARDS: JOINT CERTIFICATION

THE PROBLEM TODAY

There is currently no ecosystem of conformity assessment for digital services (Like AI) that is *equivalent* to that of tangible/manufactured products

Testing and auditing methodologies for tangible products are very different, more robust, and more time consuming than current “digital services” focused audits

If regulators continue to insert these requirements without understanding the full conformity assessment ecosystem, the probability of inserting requirements that are impossible or extremely costly and difficult to fulfill (e.g., rebuilding controls and compliance programs from the ground up) is high

IF IT DOESN'T CHANGE

Existing certifications will not be scalable for organizations without an additional "product" component due to increasing regulatory expectations

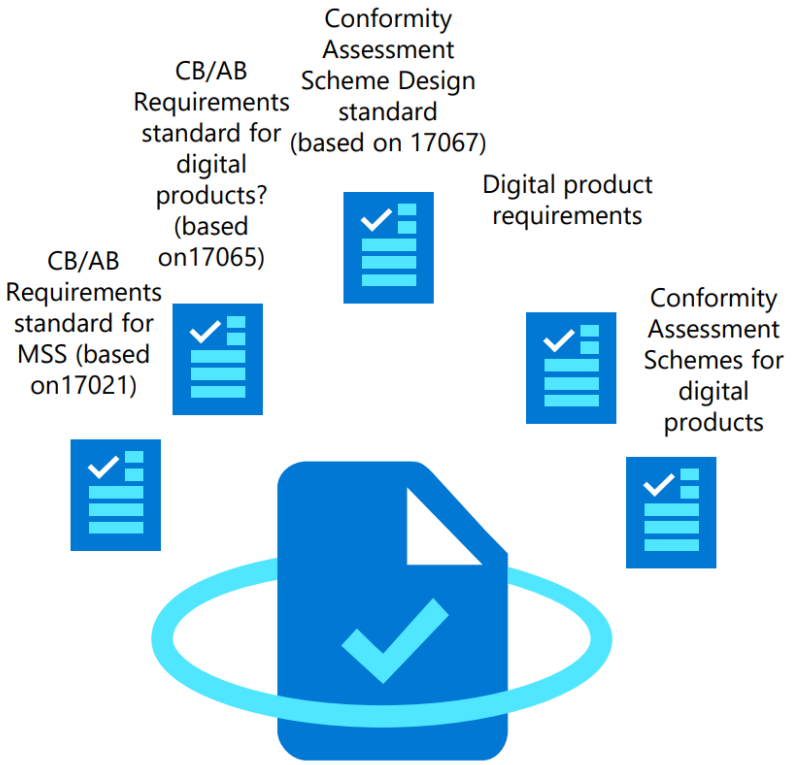
Proliferation of regional, sector-specific certifications in the absence of internationally recognized certifications for product-level assessment of digital services

Organizations faced with conformity assessment requirements they can't meet due to lack of frameworks available for digital services (e.g. schemes that can be used by certification bodies under ISO/IEC 17065 for digital services/non-tangible products)

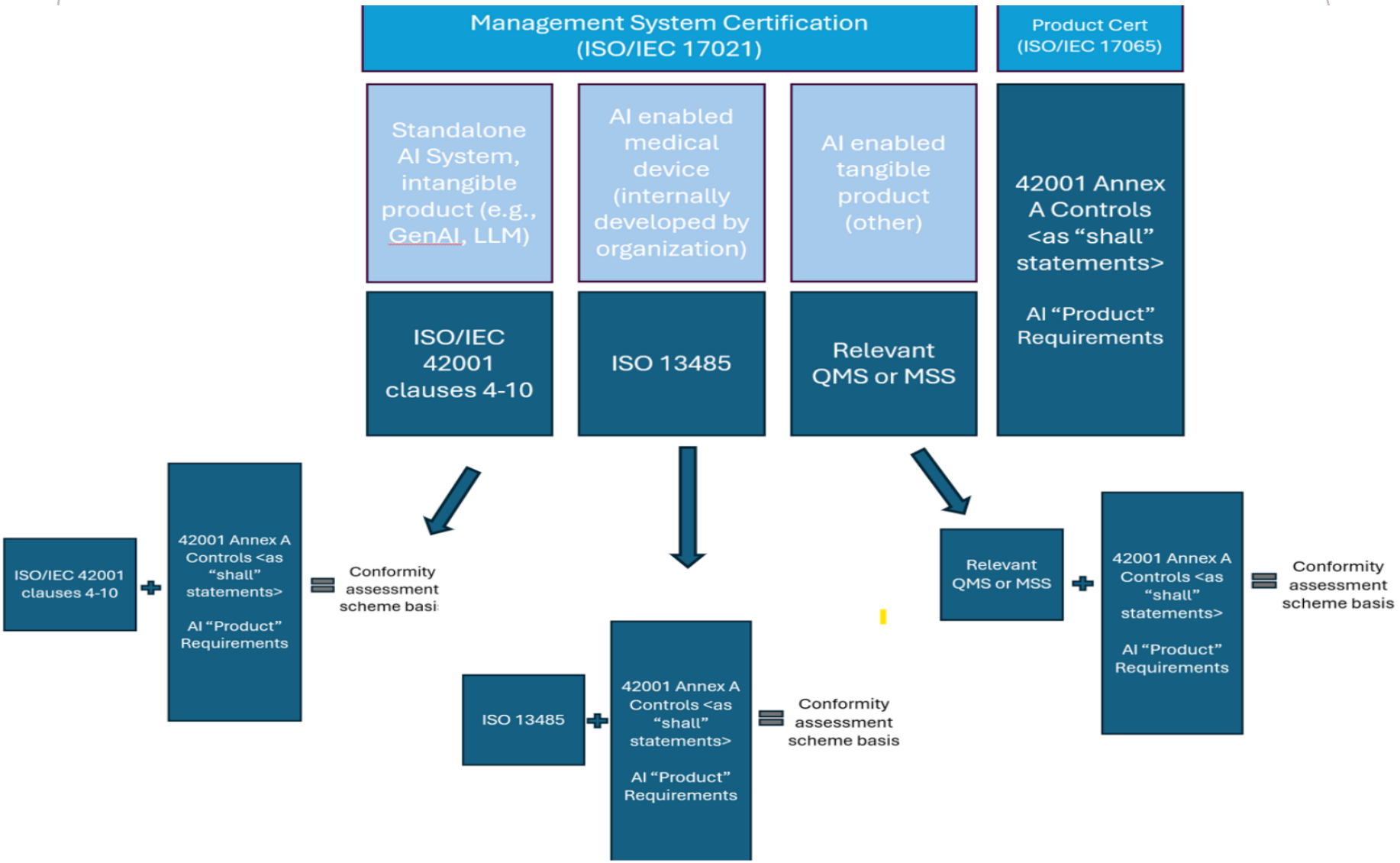
ADDRESSING THE CONFORMITY ASSESSMENT PROBLEM

- Creating a CA ecosystem for digital products
- Within that ecosystem there need to be standards such as:
  - MSS CB requirements (e.g., 27706, 27006, 42006)
  - Digital product CB requirements (This would be new.)
  - Digital product conformity assessment scheme guidance

Within conformity assessment schemes, there is the concept of "certification of digital products leveraging management system standards" (such as 42001). This is what is informally known as "joint certification."



CERTIFICATION OF DIGITAL PRODUCTS LEVERAGING MANAGEMENT SYSTEM STANDARDS : AIMS



CONTEXT

An organization that manufactures Glucose Monitors aims to embed an AI algorithm to consistently alter insulin infusion to patients in the insulin pumps.

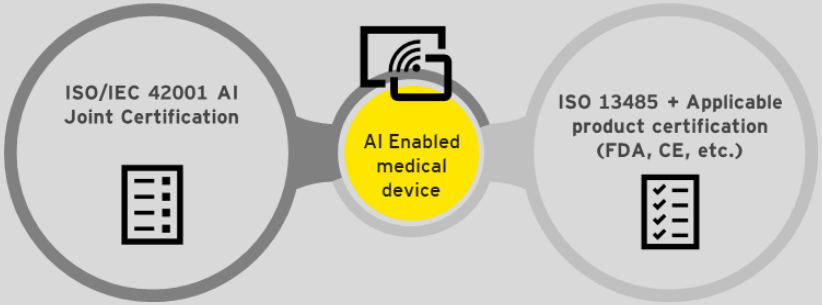
TRIGGER

The MedTech firm plans to source AI components from a third-party provider, which would be just ISO/IEC 42001 certified

KEY QUESTION

Is there a scheme that can help MedTech organizations in streamlining audits for intangible digital services along with tangible products?

SOLUTION: JOINT CERTIFICATION SCHEME BY ABC CERTIFICATION BODY



- ✓ Integrated the control requirements mentioned in ISO/IEC 42001 controls with the mandates in AI regulatory act
- ✓ Combined the scheme (ISO/IEC 42001 + AI act integration) with their 13485 certifications

ADDITIONAL INFORMATION ON JOINT CERTIFICATION

- How can the medical device industry seize the upside of changing AI regulatory requirements? (https://www.linkedin.com/feed/update/urn:li:activity:7120772491618258944/)
- A Joint certification approach to Digital Services (https://www.linkedin.com/feed/update/urn:li:activity:6914989025967689728/)

THANK YOU

Laura Lindsay

Senior Standards Strategist, Microsoft

laurali@microsoft.com

Standards Readiness Considerations

Clare Allocca

Senior Advisory for Standardization

National Institute of Standards and Technology (NIST)

Standardization Readiness and its Application

Clare M. Allocca
National Institute of Standards and Technology

NATIONAL INSTITUTE OF STANDARDS AND TECHNOLOGY
U.S. DEPARTMENT OF COMMERCE

17 July 2024

Today

- Introductions
- Standardization Readiness Concept
- Elements Description
- Standardization Strategy

Note: Standardization Readiness is an evolving concept—your input will be most welcome!

Standardization Readiness Concept

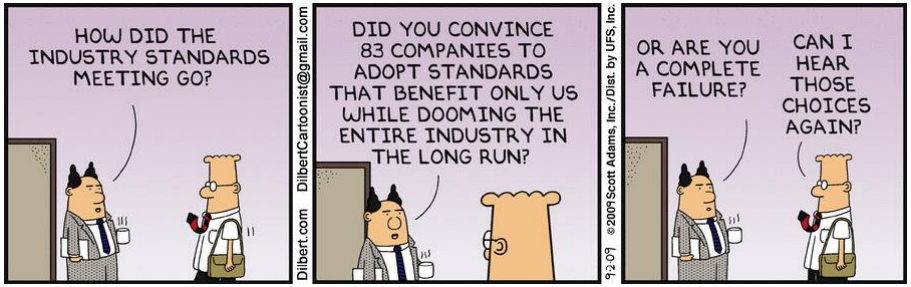
- **Standardization Readiness (SR):** a tool to inform evaluation of whether current and potential products based on an aspect of a given technology would benefit from standardization activities
- Reflects principles of standardization
  - Provides considerations for all requirements to develop a standard
  - Structures a framework for evaluation and prioritization of standardization projects and work programmes
  - Informs roadmapping and strategic initiatives
  - Provides a structured and logical means to explain standardization and evaluate ideas

How are Standards Developed?

THIS (per ISO/IEC):

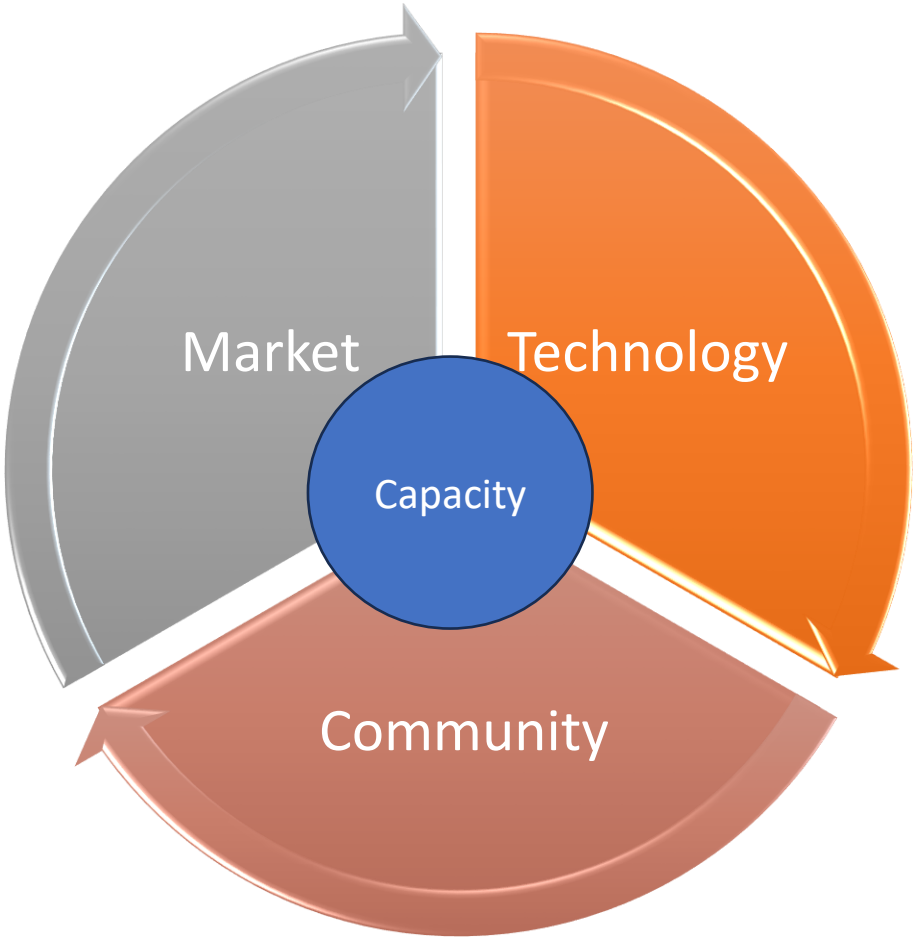
- Global Market need (implies a use case)
- Clearly defined scope with International Consensus
- Committed Global expertise from a broad array of backgrounds / locales / roles
- Sufficient technology maturity

NOT THIS:

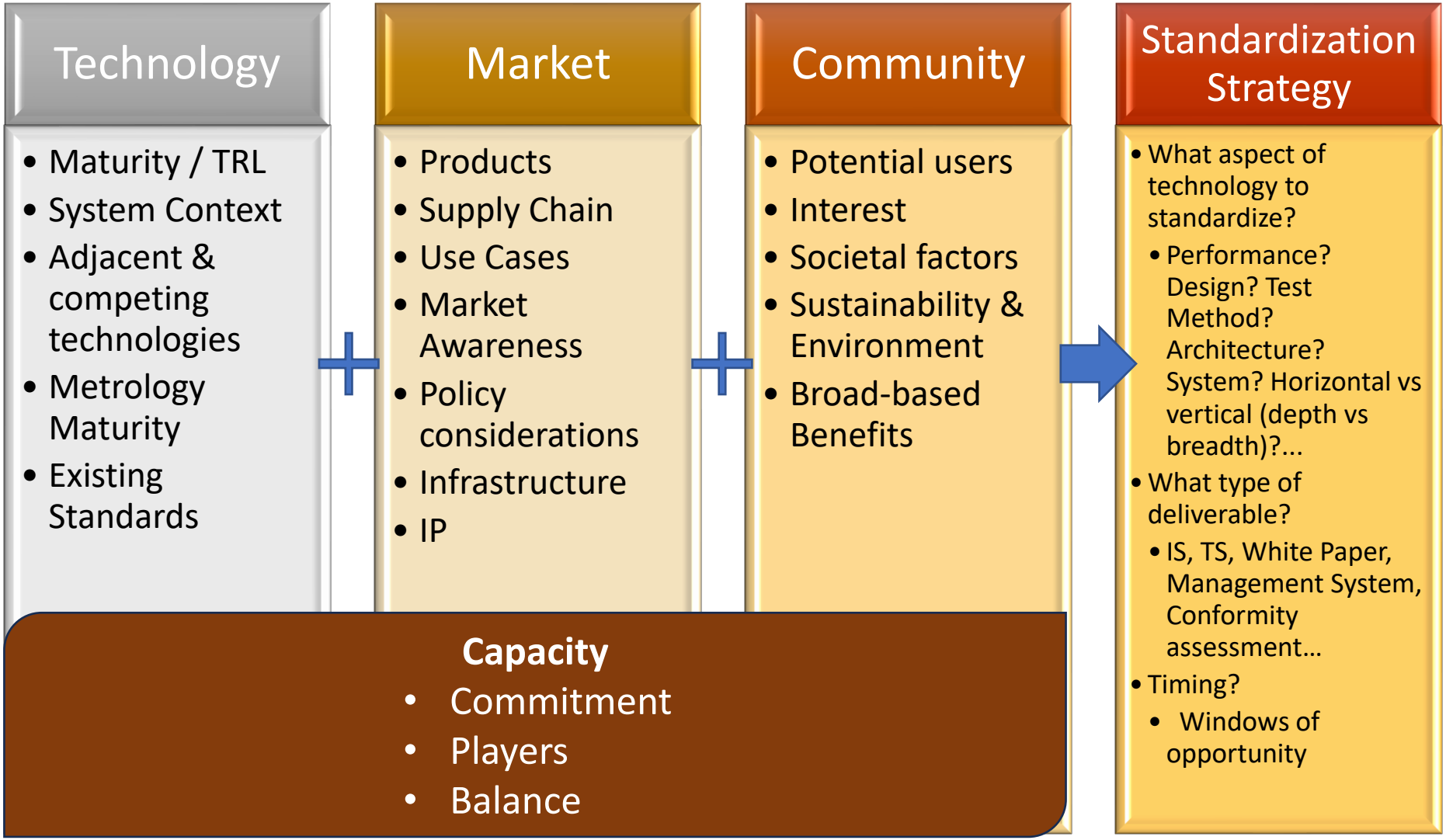


http://dilbert.com/strip/2009-09-02

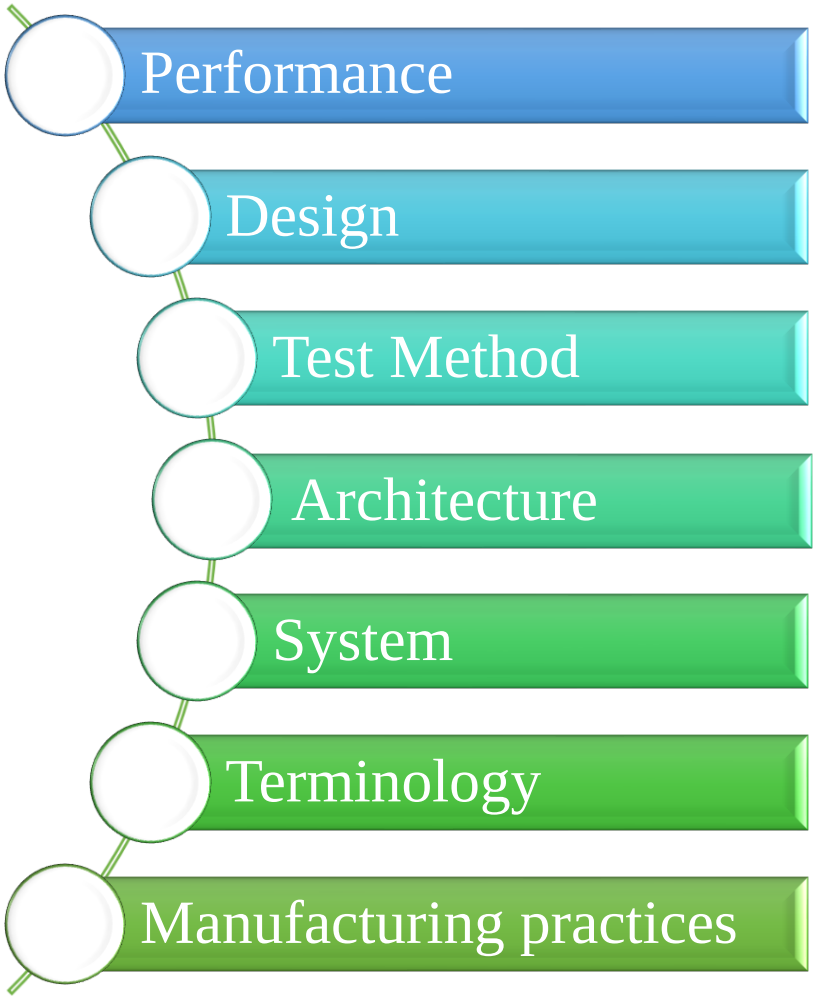
Standardization Readiness Level (SRL) Dimensions



SRL Dimensions Inform a Standardization Strategy



Informing a Standardization Strategy / Roadmap: What to Standardize?



- Value Proposition Considerations:
  - Is it appropriate to develop a technology agnostic standard that could apply to competing technologies?
  - Horizontal vs vertical standard (broad usage or specific?)
  - Are there gaps (business or technical) that would prevent usefulness of the standard(s) under consideration?

Possible responses may include, but are not limited to, System Performance; Device Design; Performance Characterization and Benchmarking; Architecture; Systems, Components, or Interfaces; Terminology and Definitions; Manufacturing Practices…

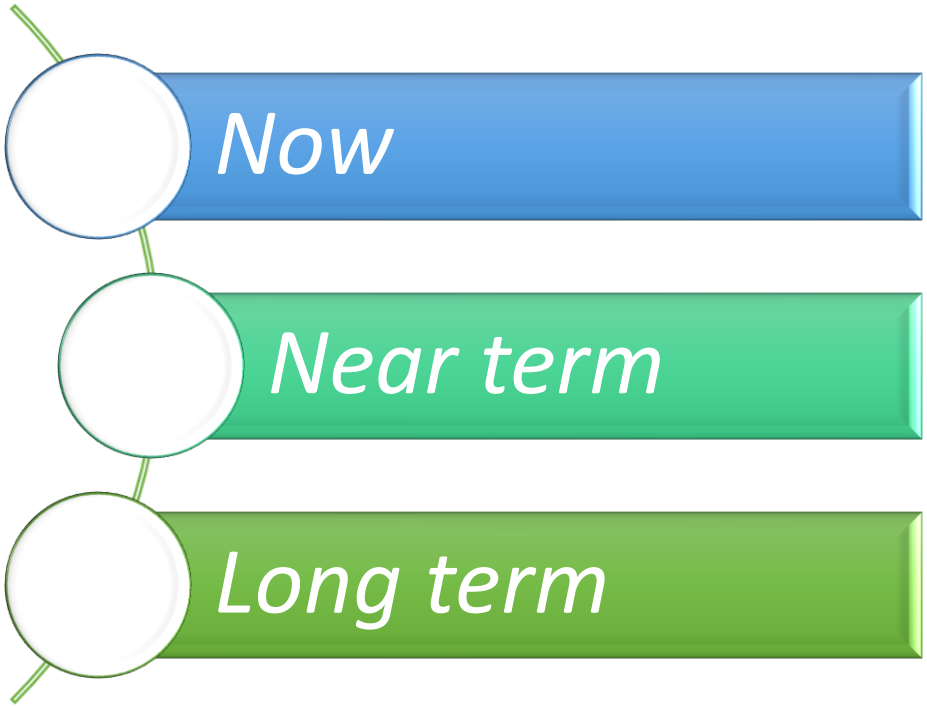
Informing a Standardization Strategy / Roadmap: In what form?

- Value Proposition Considerations:
  - How extensive are requirements?
  - Consensus level required for approval?
  - Intended Use?
  - Life limit / review cycle?
  - What level of user assurance is needed?
  - How mature and stable is the technology?

Note: In ISO/IEC, the only "standard" is an international standard (IS)
Standardization = standards and related deliverables

→ ***Normative (Requirements) or Informative (No Requirements)?***

Informing a Standardization Strategy / Roadmap: When?



- Value Proposition Considerations:
  - Windows of opportunity
  - Timing for standardization initiation and/or engagement
  - Availability of experts, interested parties

→ ***Normative (Requirements) or Informative (No Requirements)?***

Thank you

Any Questions?

Standards Readiness Phases

Christine DeJong Bernat

Associate Director, Standards Facilitation

American National Standards Institute (ANSI)

Notional Standards Readiness Phases

	PRE-STANDARDIZATION		STANDARDS DEVELOPMENT		IMPLEMENTATION
	STANDARDS READINESS PHASES				
	PREMATURE	EXPLORATORY	PLANNING	DEVELOPMENT	IMPLEMENTATION
Standards Activity	- No discussions / interest in standardization	- Identification & evaluation of existing related standards & conformity assessment programs of similar technologies - Benchmarking has begun	- Landscape & gap analysis - Roadmapping - Terminology development needed - Soliciting stakeholder engagement	- Forming standards committee - Soliciting leadership and stakeholder engagement - Developing standards	- Standards approved, maintained & utilized by industry - Conformity assessments occurring - Referenced in law or regulation, as applicable
Information Sharing & Awareness	- Internal prototyping/research has begun - Stakeholders working independently - Consortia/Association discussions not taking place, or do not exist for a particular technology	- Research has been initiated - Like-minded stakeholders sharing minimal information - Consortia/Association discussions & evaluation begun	- Research is being strategized - Like-minded stakeholders collaborating & sharing minimal information more broadly - Consortia/Association position/issue papers developed	- Research is ongoing - Balanced representation of stakeholders collaborating. - Stakeholders investing resources to draft & vote on standards. - Consortia/Association recommendations issued	- Research is ongoing - Balanced representation of stakeholders collaborating & doing business - Stakeholders investing resources to draft & vote on standards. - Consortia/Association advocating for standards adoption

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Discussion Preparation: Challenges, Opportunities, and Standards Readiness

Establishing a Baseline

- What are the **challenges** and **opportunities** presented by AI and is there sufficient public and private stakeholder awareness on these fronts?
- What **role** do stakeholders see **standards** playing in overcoming challenges?
- What concerns have been raised about existing standards efforts?
- Does the sector need to see AI **standards development accelerated**?
- What approaches could be taken to help **align/maintain the pace** of AI standards and technology development?
- What is the role of **industry vs government** to maximize opportunities?
- What **regulation, policy and/or conformity assessment** frameworks might be needed to enable or accelerate technology uptake?
- What is the role of government to maximize opportunities? To support standards development?

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BREAK

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Session 2: Healthcare Challenges, Opportunities, and Standards Readiness

Moderator

Shawn Forrest
Digital Health Specialist
U.S. Food and Drug Administration
(FDA)

AI & Machine Learning in Healthcare Discussion

Challenges, Opportunities, and Standards Readiness

- **What are the challenges and opportunities presented by AI and is there sufficient public and private stakeholder awareness on these fronts?** (Slido)
- What role do stakeholders see standards playing in overcoming challenges? (Slido)
- What is the role of industry vs government to maximize opportunities? (Slido)
- What regulation, policy and/or conformity assessment frameworks might be needed to enable or accelerate technology uptake? (Slido)
- What is the role of government to maximize opportunities? To support standards development?

AI in Healthcare

Opportunities

- Support public health emergency preparedness & response
- Assist pattern analysis in medical images
- Clinical decision support
- Information modeling improvements
- Revalidation processes (for healthcare models)
- Reduce repetitive work / human errors
- Support clinical workflows & electronic health/medical record platforms
- Faster results

Challenges

- Trust
- Data/algorithmic bias
- Determination of liability
- Standardizing practices for patients and providers
- Privacy of health data
  - Especially in use of data for training
- Transparency in AI decision-making

AI & Machine Learning in Healthcare Discussion

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AI & Machine Learning in Healthcare Discussion

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AI & Machine Learning in Healthcare Discussion

What regulation, policy and/or conformity assessment frameworks might be needed to enable or accelerate technology uptake?

- Uniform standard essential patent (SEP) policy statement to mitigate abusive SEP licensing conduct
- AI framework for public health & healthcare emergency preparedness/surveillance
- Legislation on transparency of use
- AI risk controls (ISO/IEC 42001)
- Regulation should follow technology development, not come before it
- Ranking systems for large language model (LLM) platforms
- Regulation on water-marking AI generated contents
- Defining what is proprietary data
- Alignment on core safety and security needs
- Health data privacy rules to protect patients

AI & Machine Learning in Healthcare Discussion

Challenges, Opportunities, and Standards Readiness

- What are the challenges and opportunities presented by AI and is there sufficient public and private stakeholder awareness on these fronts?
- What role do stakeholders see standards playing in overcoming challenges?
- What is the role of industry vs government to maximize opportunities?
- What regulation, policy and/or conformity assessment frameworks might be needed to enable or accelerate technology uptake? (Slido)
- **What is the role of government to maximize opportunities? To support standards development?**

LUNCH

11:45 - 12:45 PM

Session Agenda

SESSION 1: TECHNOLOGY CONVERGENCE AND STANDARDS READINESS BRIEFINGS	
9:30 – 10:10 am	Presentations
SESSION 2: CHALLENGES, OPPORTUNITIES, AND STANDARDS READINESS DISCUSSION	
10:10 – 10:25 am	Discussion Preparation: Challenges, Opportunities, and Standards Readiness
10:25 – 10:40 am	Networking Break
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12:45 – 1:30 pm	**AI & Machine Learning in Manufacturing Discussion**
SESSION 3: STANDARDS DRIVEN PUBLIC-PRIVATE PARTNERSHIPS (PPPS)	
1:30 – 1:40 pm	**Discussion Preparation: PPP Enabling CETs**
1:40 – 2:10 pm	**Standards Driven Public-Private Partnership Models Briefings**
2:10 – 3:15 pm	**Public-Private Partnerships: Enabling CETs Discussion**
3:15 – 3:30 pm	**Networking Break**
SESSION 4: INFORMATION SHARING NECESSARY TO SUPPORT CET STANDARDS DEVELOPMENT	
3:30 – 3:50 pm	**Current State of Information Sharing Briefings**
3:50 – 4:30 pm	**Future State of Information Sharing Discussion**
4:30 – 5:00 pm	**Key Takeaways & Closing Remarks**

Session 2: Manufacturing Challenges, Opportunities, and Standards Readiness

Moderator

Franck Journoud
Senior Director, Technology Policy
National Association of Manufacturers (NAM)

AI & Machine Learning in Manufacturing Discussion

Challenges, Opportunities, and Standards Readiness

- **What are the challenges and opportunities presented by AI and is there sufficient public and private stakeholder awareness on these fronts?** (Slido)
- What role do stakeholders see standards playing in overcoming challenges?
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AI in Manufacturing

Opportunities

- Novel redesigns of conventional parts
- Restoring workflows or production lines
- Asset, process & system monitoring and/or oversight
- Maintenance prediction & reporting
- Quality control
- Fraud detection & prevention
- Increase data collection
- Create benchmarks & testing protocols to assess safety, performance, etc.
- Information retrieval for reporting

Challenges

- IP protection
- Trust
- Data quality
- Risk analysis / ROI practices
- Integrating into safety standards / functions
- Data / algorithmic bias
- Training
- Monitoring effects of AI decision-making

AI & Machine Learning in Manufacturing Discussion

Challenges, Opportunities, and Standards Readiness

- What are the challenges and opportunities presented by AI and is there sufficient public and private stakeholder awareness on these fronts?
- **What role do stakeholders see standards playing in overcoming challenges? (Slido)**
- **What is the role of industry vs government to maximize opportunities? (Slido)**
- What regulation, policy and/or conformity assessment frameworks might be needed to enable or accelerate technology uptake? (Slido)
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AI & Machine Learning in Manufacturing Discussion

Challenges, Opportunities, and Standards Readiness

- What are the challenges and opportunities presented by AI and is there sufficient public and private stakeholder awareness on these fronts?
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- **What regulation, policy and/or conformity assessment frameworks might be needed to enable or accelerate technology uptake?** (Slido)
- What is the role of government to maximize opportunities? To support standards development?

AI & Machine Learning in Manufacturing Discussion

What regulation, policy and/or conformity assessment frameworks might be needed to enable or accelerate technology uptake?

- Data protection principles – ways to share data without legal issues
- Uniform standard essential patent (SEP) policy statement to mitigate abusive SEP licensing conduct
- Legislation on transparency of use
- AI risk controls (ISO/IEC 42001)
- Regulation should follow technology development, not come before it
- Ranking systems for large language model (LLM) platforms
- Regulation on water-marking AI generated contents
- Alignment on core safety and security needs

AI & Machine Learning in Manufacturing Discussion

Challenges, Opportunities, and Standards Readiness

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Session 3 Discussion Preparations

Public-private partnerships (PPPs) are collaborations between a government agency and a private-sector organization for the purposes of delivering a project or service, and which involve the sharing of resources, responsibility, risks, and benefits.

Standards-Driven Public-Private Partnerships

Standards-driven PPPs (SD-PPPs) are a type of PPP where resources invested are directly impacting consensus-based standards development.

- SD-PPPs may or may not involve contractual agreements, financial support, or formal relationships between public and private representatives.
- SD-PPPs may prove more effective when private-sector technology and innovation synergizes with public-sector priorities and incentives.
- Common work products of SD-PPPs are:
  - **Pre-standardization activities**: Roadmaps, gap analysis, research and development, etc.
  - **Standards development**: Support for the proposal and/or formation of new committees, identifying and convening technical experts, content development, etc.
  - **Implementation**: Increasing awareness, technical training, workforce development, conformity assessment, etc.

- **Actual SD-PPP use cases often include the characteristics of more than one model. For example, a SD-PPP may be a "standards acceleration" and a "funded participation model."**

Enabling Artificial Intelligence and Machine Learning Through Public-Private Partnerships

SD-PPP Models

- Direct-Participation
- Standards Acceleration
- Funded Participation
- Funded Standards Development
- Policy and Conformance Driven

SD-PPP: Direct Participation

Public sector directly participates in the standards development process alongside to any other stakeholder at the table. As with any other participant, they represent their organization and follow any policies set forth by their employer as well as the regulations/bylaws of the SSO supporting the standards development activity. Policies and guidance about federal government participation can be found in Public Law 104-113, National Technology Transfer and Advancement Act of 1995, and OMB Circular A-119, Federal Participation in the Development and Use of Voluntary Consensus Standards and in Conformity Assessment Activities.

Objectives	- Support the development of standards - Provide insight about what role standards would play in relation to existing or future government regulations/policy - Gather information to inform potential government regulations/policy
Work Products	- Pre-standardization: technical reports, strategic plans - Standardization: Standards development - Implementation: Increasing awareness, technical training, workforce development on standards

SD-PPP: Standards Acceleration

A standards acceleration SD-PPP is primarily focused on convening stakeholders to discuss opportunities, challenges, and needs for a given technology and applicable sectors. The primary objective of this SD-PPP activities may not be to develop standards but instead support pre-standardization efforts. Ultimately, the desired outcome is to determine if there is consensus about the need for standards, and help advance decision-making and therefore accelerate subsequent standards development.

Objectives	- To accelerate the development of standards by convening experts to increase awareness about existing and needed research and standards.
Work Products	- Pre-standardization: Technical workshop and symposia, standards road mapping (landscaping and gap analyses), and other research and technology reports.

SD-PPP: Funded Participation

A funded participation SD-PPP is utilized to increase participation of subject matter experts in the standards development process. Often, startups, small or medium companies in new or niche technology areas have limited resources to travel and participate in standards; or the sector has not yet established enough resources to have as many subject matter experts who have longstanding knowledge and experience both in the field and in standards development. Both of these resource constraints can delay standards development or impact a balance of representation. In order for this to be a PPP, some funding for individuals to participate would need to come from the government but may also come from the private sector.

Objectives	- Support increased participation to balance the representation of stakeholders in an activity including small and medium organizations, startups or key technical experts without the resources to pay participation (membership/event) fees or travel.
Work Products	- N/A, this supports standards development but the objective is not a tangible work product.

SD-PPP: Funded Standards Development

A funded standards development SD-PPP is utilized when stakeholders need resources to conduct research, testing, or data gathering to help inform and develop standards. The activities may result in content development (such as test methods, best practices or design requirements), technical presentations at a SSO meeting, or help with anonymizing information so industry data can be shared without revealing IP. In some cases, funding is allocated to an organization or to an individual with the objective of drafting a standard(s).

Objectives	- Accelerate standards development by funding initial research
Work Products	- Pre-standardization: Research, research reports, databases, statistics - Pre-standardization: Formation of a new standards developing committee or SDO - Standards Development: Draft proposed test methods, design specification, best practices - Implementation: Increasing awareness, technical training, workforce development on standards

SD-PPP: Policy & Conformance Driven

A policy and conformance driven SD-PPP is utilized when the public and private sector collaborate to develop standards specifically to meet a new regulation, policy, or conformity assessment requirement. Initiation of this SD-PPP may also be the result of an emergency situation (e.g., pandemic or incident involving fatalities). This SD-PPP stands out as its own model solely because it requires rapid development of one or more standards and dedicate resources to accomplish this in a specific timeline. This scenario typically involves a combination of characteristics described in the Direct Participation, Standards Acceleration and Funded Participation SD-PPP models.

Objectives	- Enable or accelerate standards development to support an anticipated new regulation or certification requirement. The standards are expected to be incorporated by reference.
Work Products	- Pre-standardization: Strategic plans and roadmaps - Standards Development: Standards (1 or more standards) - Implementation: Increasing awarness, technical training, worforce development on standards

Session 3 SD-PPP Briefings

Government Perspective

Natalia Globus Martin

Deputy Director for National Cybersecurity Center of Excellence (NCCoE)

National Institute of Standards and Technology (NIST)

SDO Perspective

Rohit Israni

CEO of CertientAI

& Chair of INCITS/AI

Industry Perspective

Kerri Haresign

Sr. Director in the Technology & Standards

Consumer Technology Association (CTA)®

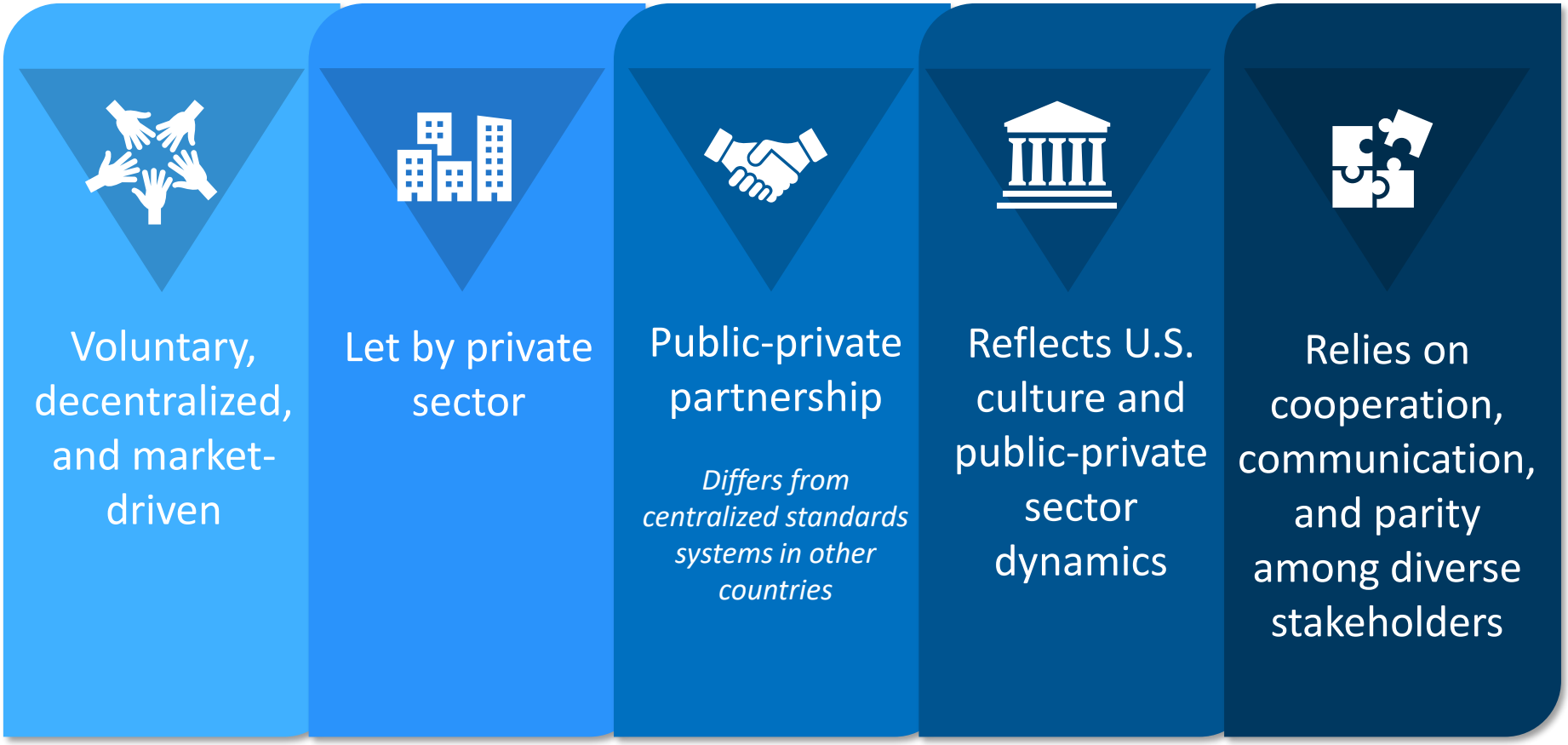
NATIONAL INSTITUTE OF STANDARDS AND TECHNOLOGY
U.S. DEPARTMENT OF COMMERCE

Standards and Technology Driven Public-Private Partnership Models

Natalia Globus Martin
National Institute of Standards and Technology

July 2024

U.S. Standardization "System"



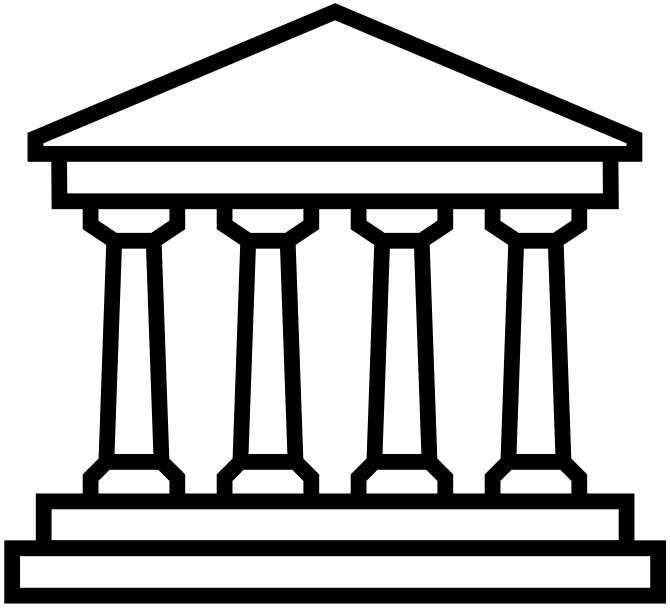
Innovation Stakeholders

U.S. leadership in the U.S. innovation ecosystem requires collaboration among a diverse set of participants.

USG Standards Mandate

USG law and policy requires Federal agencies to use **international**, **voluntary**, **consensus** standards in their procurement and regulatory activities, except where inconsistent with law or otherwise impractical

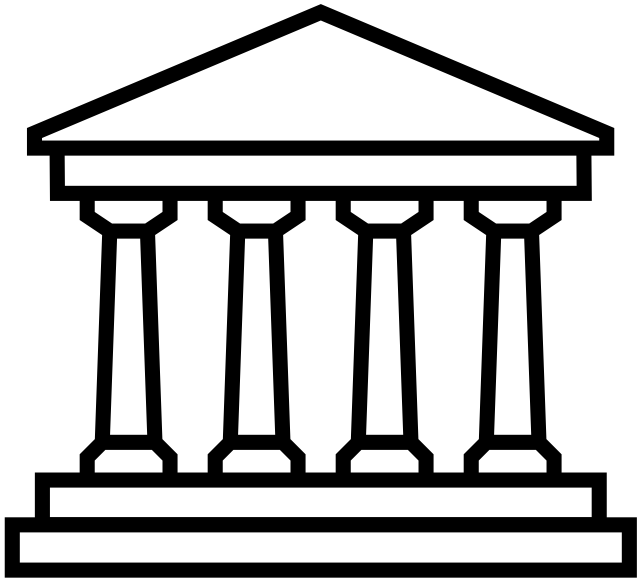
- National Technology Transfer and Advancement Act (NTTAA)
- OMB Circular A-119
- Trade Agreements Act (TTA) of 1979
- M-12-08, Principles for Federal Engagement in Standards Activities to Address National Priorities (memo from three EOP offices: OSTP, OMB/OIRA and USTR)



USG Technology Transfer Mandate

Federal Technology Transfer is transfer of knowledge developed by Federal agencies concerning tools, materials, application techniques and problem-solving methods, to the private sector for commercialization

- Stevenson-Wydler Technology Transfer Act of 1980
- Bayh–Dole Act or Patent and Trademark Law Amendments Act, December 12, 1980
- CRADA Statute 15 USC 3710a (tech transfer)

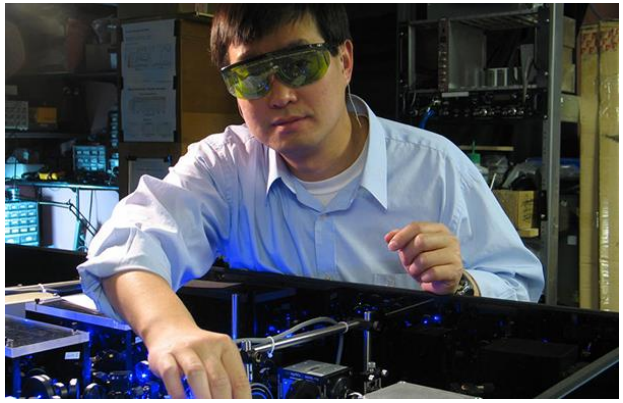


How does USG get Technology to Transfer?

- By-products of mission-oriented R&D at Federal labs
- Developed at universities and private sector firms through Federally funded collaborations and contract projects
- Developed through non-R&D mission-related engineering and technical activities, e.g., equipment maintenance, performance testing, regulatory compliance, enforcement investigations
- Clever people working on routine technical problems often come up with innovative solutions and discoveries having commercial value

NIST Mission

To promote U.S. innovation and industrial competitiveness by advancing measurement science, standards, and technology in ways that enhance economic security and improve our quality of life



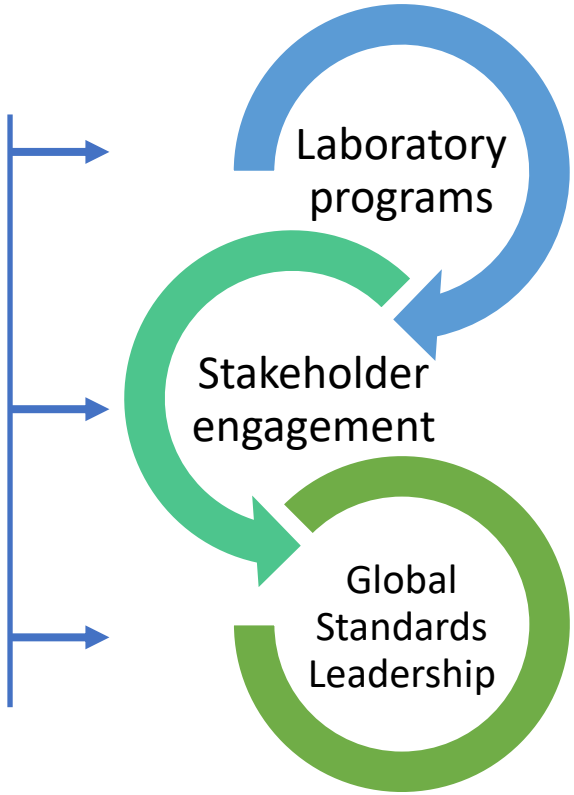
NIST is the US Government's premier agency for measurement, research, and standards development

From Laboratory Programs to Standards

NIST Core Laboratory Capabilities

Consortia & CRADA partners, USG, NMIs, NGOs & other strategic partnerships

SDOs: ISO, IEC, OECD, WHO, ASTM, PDA, etc.
Professional societies



In house capabilities & expertise to support the rapidly evolving technologies

- **Pre-competitive technology, measurement solutions, reference materials and ref. data, etc.**
- **Ongoing bilateral collaborations with industry partners**

- **Supports innovation and commerce**
- **Supports WHO & global regulatory convergence**

Benefits of Using Consortia CRADA

A consortia CRADA allows to work with multiple industry partners at once on a single project with benefit to all parties. Consortia are particularly useful for developing standards/references and addressing issues that affect an entire industry sector.

- Ease of entering into a formal arrangements
- Access to Federal laboratories' expertise, capabilities, and technologies to foster innovation and improve the Unites States' economic, environmental, and social well-being
- Access to IP resulting from the CRADA effort
- Reduced costs, time, and risk of R&D to achieve mission and/or commercial goals by leveraging external expertise, ideas, investment, and resources

Examples Various Models of PPP that enable standards development at NIST

	Mechanism	Stakeholders	Drivers for partnering
Quantum Economic Development Consortium (QED-C)	Consortium under Other Transaction Authority	SRI International, DOE, 180 companies	Support the emerging quantum-based industry
National Institute for Innovation in Manufacturing Biopharmaceuticals (NIIMBL)	Cooperative Agreement	USA Bio Consortium (150 members), University of Delaware	Accelerating innovation in biopharmaceutical manufacturing industry sector
National Cybersecurity Center of Excellence (NCCoE)	FFRDC + CRADA + MOU	MITRE, industry and academia participants in projects, corporation of technology partners	Address industry's most pressing cybersecurity issues
The Center for Statistics and Applications in Forensic Evidence (CSAFE)	Cooperative Agreement	Led by Iowa State University with partners Carnegie Mellon University, University of Virginia, and University of California-Irvine.	Establish scientific foundation for analytical techniques used in forensics
IBBR	Cooperative Agreement, MOU	University of Maryland, College Park; and University of Maryland, Baltimore	Advance measurement science in biotechnology

Artificial Intelligence (AI) Standards

Rohit Israni

7/17/2024

US and ISO/IEC JTC 1/SC 42

- US is focused on developing international AI standards
- US stakeholders led the formation of international AI Standards committee ISO/IEC JTC 1 SC 42; US holds chair and committee management positions
- US companies, institutions and govt. agencies (including NIST, NSA, FDA,DoD) are participating actively in SC 42

Promoting U.S. Leadership in International Standards

- Allocate increased R&D funding for critical and emerging technologies
- Encourage the USG to broadly promote the voluntary, private sector led standards development model domestically and in dialogues and agreements with other countries
- Encourage greater participation by federal agency staff in mission-relevant international standards development activities

Consumer Technology Association™

CES®

Enabling Artificial Intelligence and Machine Learning Brainstorming Session

Standards Drive Public-Private Partnership Model

Kerri Haresign

Sr. Director, Technology & Standards

Who We Are

- CTA is the trade association representing the $505 billion U.S. consumer technology industry, which supports more than 18 million U.S. jobs.
  - 1300+ Member Companies
  - 30+ Research Reports
  - 20+ Special Focus Divisions, Councils, and Working Groups
  - 130+ Standards
  - Owners and Producers of CES – The Most Powerful Tech Event in the World
- Our Mission: To help Innovators of all sizes grow their business.

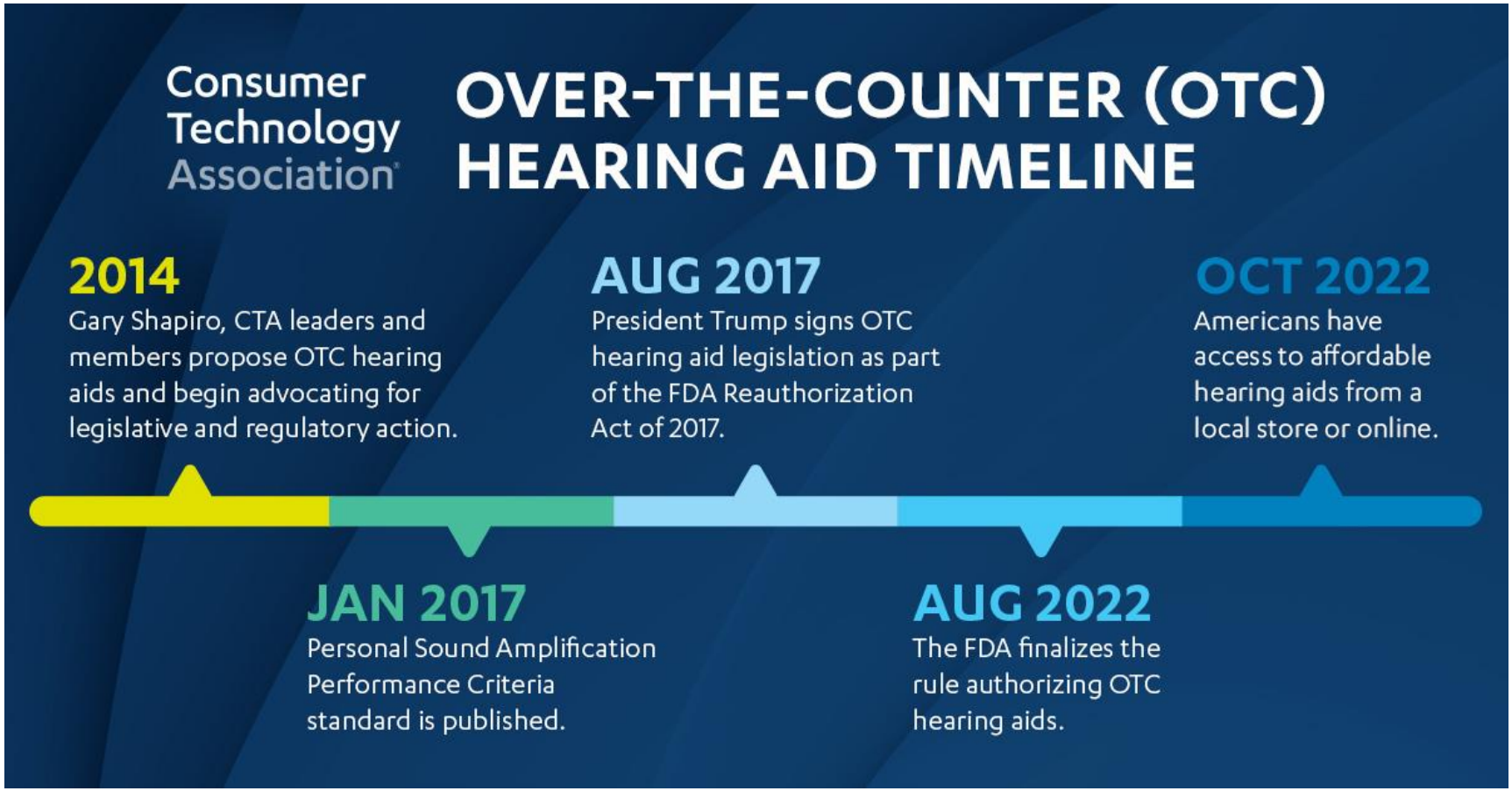
Artificial Intelligence Standardization

- Horizontal
  - Definitions and Characteristics of Artificial Intelligence (CTA-2089-A)
  - Cybersecurity Threats and Security Controls for Machine Learning Based Systems (CTA-5203)
  - Guidelines for Developing Trustworthy Artificial Intelligence Systems (ANSI/CTA-2096)
- Healthcare
  - Artificial Intelligence in Health Care: Practices for Identifying and Managing Bias (ANSI/CTA-2116)
  - The Use of Artificial Intelligence in Health Care: Managing, Characterizing, and Safeguarding Data (ANSI/CTA-2107-A)
  - Definitions/Characteristics of Artificial Intelligence in Health Care (ANSI/CTA-2089.1)
  - The Use of Artificial Intelligence in Health Care: Trustworthiness (ANSI/CTA-2090)

CTA's AI Advocacy

- CTA believes that existing legal authorities apply to the use of automated systems and AI just as they apply to other practices. This was emphasized in last year's joint statement by DOJ, EEOC, FTC, and CFPB.
- CTA supports ethical and responsible AI through industry standards, risk management, and national AI policy.
- Policy should recognize that AI is improving lives and solving big global problems.
- Learn more.

Public Private Partnerships: Example One



Public Private Partnership: Example Two

- A public-private sector effort is developing a voluntary cybersecurity label program for consumer connected devices (consumer IoT).
- The effort is led by the White House and FCC, with input from CTA, the National Institute of Standards and Technology (NIST) and other government and private sector stakeholders.
- The U.S. Cyber Trust Mark program will give consumers more information about the cybersecurity of the connected products they buy and ensure that those products meet certain standards.
- The following draft standards are being proposed for incorporation by reference, and CTA is closely coordinating with FCC on details.
  - ANSI/CTA-2119, Framework for Evaluation of a Cybersecurity Scheme
  - CTA-2120, Design Requirements for a Label for IoT Device Cybersecurity
  - CTA-2126, Guidelines for the National Cybersecurity Label Conformity and Trust Programs

Public Private Partnership: Example Three

- Voluntary Agreement – Energy Efficiency of TVs
  - Determination of Televisions Set Power Consumption (ANSI/CTA-2037-D)

Contact

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Kharesign@cta.tech

Questions?

Session 3: Standards-Driven Public-Private Partnerships (PPPs)

Moderator

Amanda Benedict
Vice President, Sterilization
Association for the Advancement of Medical Instrumentation (AAMI)

SD-PPPs Discussion

- What benefits or challenges do you see with a PPP for these technologies? (Slido)
- What role can various types of stakeholder organizations play in PPPs for these technologies?
  - e.g., consortia, trade associations, academia, standards organizations, centers of excellence
- What PPP short-term and long-term goals would have the broadest impact on success? (Slido)
  - e.g., standards focused R&D, workforce development, research and standards roadmaps, strategic planning
- What type of PPP model or models could benefit these technologies? (Slido)
- At what (if any) point would an organized PPP activity be most advantageous? (Slido)
- Does a PPP require a formal agreement to be able to realize its purpose?

Standards-Driven Public-Private Partnerships for AI

Benefits

- Increase investment & resource allocation
- Improve standards & regulatory alignment
- Develop trust & integrity in tools
- Foster transparency & accountability
- Diverse perspectives come together
- Increased coordination on standards, policy, training, etc.
- Accelerated R&D, standards, and resource integration
- Avoiding duplication
- Establishes platform for testing innovation

Challenges

- Differing objectives & priorities
- Complex governance & management
- Data sharing / privacy concerns
- Information sharing –
  - Fear of losing IP
  - Fear of sharing with government
- Bureaucratic hurdles of partnership
- Ensuring adequate & balanced representation of stakeholders
- Conflict between short-term profit and long term technical goals
- Speed
- Obtaining funding & resources
- Competition between public and private sectors

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Enabling Artificial Intelligence and Machine Learning Through Public-Private Partnerships

SD-PPP Models

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BREAK

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3:50 – 4:30 pm	**Future State of Information Sharing Discussion**
4:30 – 5:00 pm	**Key Takeaways & Closing Remarks**

Session 4: Information Sharing Necessary to Support Standards Development

Current State of Information Sharing Briefings
20 minutes

Presenters:
- Mary Saunders, ANSI
- Natalia Globus-Martin, NIST

Future State of Information Sharing Discussion
40 minutes

Moderator:
- Muhammad Ali, HP, Inc.

Session 4: Current State of Information Sharing Briefings

What information is being shared today?

Mary Saunders

Senior Vice President for Government Relations and Public Policy

American National Standards Institute

What did industry suggest in RFI responses and past listening sessions?

Natalia Globus Martin

Deputy Director for National Cybersecurity Center of Excellence (NCCoE)

National Institute of Standards and Technology (NIST)

What Information is Being Shared Today?

Enabling AI and Machine Learning Through Public-Private Partnerships – July 17, 2024

Information Resources

- SDO Standards Portfolios
  - Overviews by technology area (existing and planned standards)
  - How to participate
- Standards Landscapes
  - By technology area – compilation of current activities
  - Produced by the private sector, government agencies
- Assessments/Studies
  - Private sector- and government-authored
  - Collection/synthesis of standards-related data
- Standards Coordination Roadmaps
  - to assess and address standardization needs in a particular industry or technology area
  - identify existing standards and standards in development
  - define where standards gaps exist
  - intended to inform resource allocation, avoid duplication of effort, and coordinate standards actions

ANSI Standards Action

- *Standards Action* provides timely, accurate information about current standards development work in which ANSI plays a role.
- The publication is designed to facilitate participation in the American National Standards (ANS) development process as well as other domestic, regional, and international standardization activities advanced by ANSI.
  - Includes current work underway at the International Organization for Standardization (ISO), the International Electrotechnical Commission (IEC), and ISO/IEC Joint Technical Committee (JTC) 1, through U.S. Technical Advisory Groups (TAGs)
- Each weekly edition – available by download or free email subscription – comprises a round-up of the latest information available to help all interested parties get informed and engaged in standards.

ANSI Standardization Collaboratives

Advance **cross-sector coordination** in the standards and conformance programs needed to support and grow **emerging technologies and markets**

Active Collaboratives:

- **2017:** Unmanned Aircraft Systems Standardization Collaborative
- **2016:** America Makes & ANSI Additive Manufacturing Standardization Collaborative
- **2011:** ANSI Electric Vehicles Standards Panel
- **2004:** Nanotechnology Standards Panel
- **2003:** Homeland Defense and Security Standardization Collaborative

Previous Collaboratives:

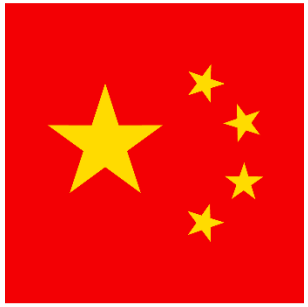
- **2013:** ANSI Network: Smart and Sustainable Cities
- **2012:** ANSI Energy Efficiency Standards Coordination Collaborative
- **2010:** ANSI-NIST Nuclear Energy Standards Coordination Collaborative
- **2010:** The Financial Management of Cyber Risk
- **2007:** ANSI Network on Chemical Regulations
- **2007:** Biofuels Standards Coordination Panel
- **2006:** ID Theft Prevention and ID Management Standards Panel
- **2005:** Healthcare Information Technology Standards Panel
- **1994:** Information Infrastructure Standards Panel

Global AI Standards Landscape

ISO/IEC JTC1/SC 42
Horizontal ICT AI Standards

Significant initiative on Ethics

Focus on telecom networks & some applications



Comprehensive national AI standards, participation in ISO/IEC, ITU

EU AI Act driving EU-specific standards, collaborating with ISO/IEC

US and ISO/IEC JTC 1/SC 42

- US is focused on developing international AI standards
- US stakeholders led the formation of international AI Standards committee ISO/IEC JTC 1 SC 42; US holds chair and committee management positions
- US companies, institutions and govt. agencies (including NIST, NSA, FDA) are participating actively in SC 42

JTC 1/ SC 42 work program examples

Published	Under development
• AI concepts and terminology • Governance implications on use of AI • Guidance on Risk Management • Overviews of trustworthiness, bias, ethical and societal concerns • Framework for machine learning systems • Assessments of robustness, ML classification performance • AI Management System	• Functional safety and AI systems • Guidance for explainability, transparency, mitigating unwanted bias • Data quality management and governance • AI system testing, verification and validation, quality models, functional safety, lifecycle • Oversight of AI systems • AI applications, beneficial use cases • Environmental sustainability aspects

50 Countries

1 Country 1 Vote

33 Active Projects

30 Published

40+ Liaisons

Sector-focused Standards

- In industries that are coming to rely heavily on AI, sector-specific standards projects are also beginning to emerge in ISO and IEC committees, as well as in other venues:
  - Automotive/aerospace: *SAE International, ULSE*
  - Financial Services: *Accredited Standards Committee X9*
  - *Healthcare: AAMI, ADA, CTA, DICOM, etc.*
  - Consumer IoT: *CTA, etc.*
  - Biotechnology: *American Type Culture Collection*

Objectives for AI Standards Engagement

- Scientifically sound standards that are accessible and amenable to adoption
- Standards that reflect the needs and input of diverse global stakeholders
- Standards that are developed in a process that is open, transparent, and driven by consensus
- International relationships that are strengthened by engagement on AI standards

Private Sector Priorities

- Regular government engagement with private sector stakeholders on both AI-related technical issues and broader AI standards and policy discussions
- Government recognition that many priority interactions will depend on private-sector leadership and joint efforts from the global AI and standards communities.
- Consideration of the full standards lifecycle—including research and related technical activities—as well as the full range of issues, both technical and societal, associated with standards for AI applications

Contact Information

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ANSI
American National Standards Institute

NATIONAL INSTITUTE OF STANDARDS AND TECHNOLOGY
U.S. DEPARTMENT OF COMMERCE

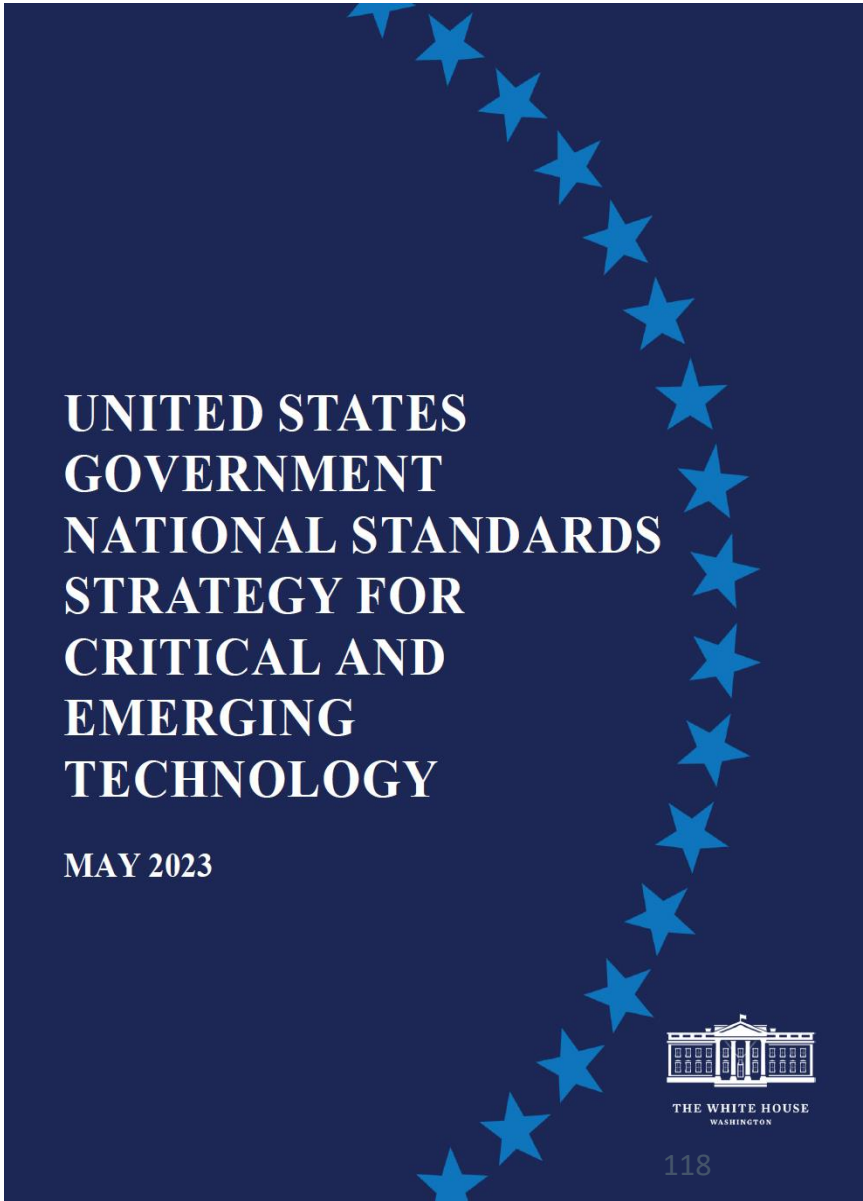
Information Sharing Necessary to Support CET Standards Development

July 2024

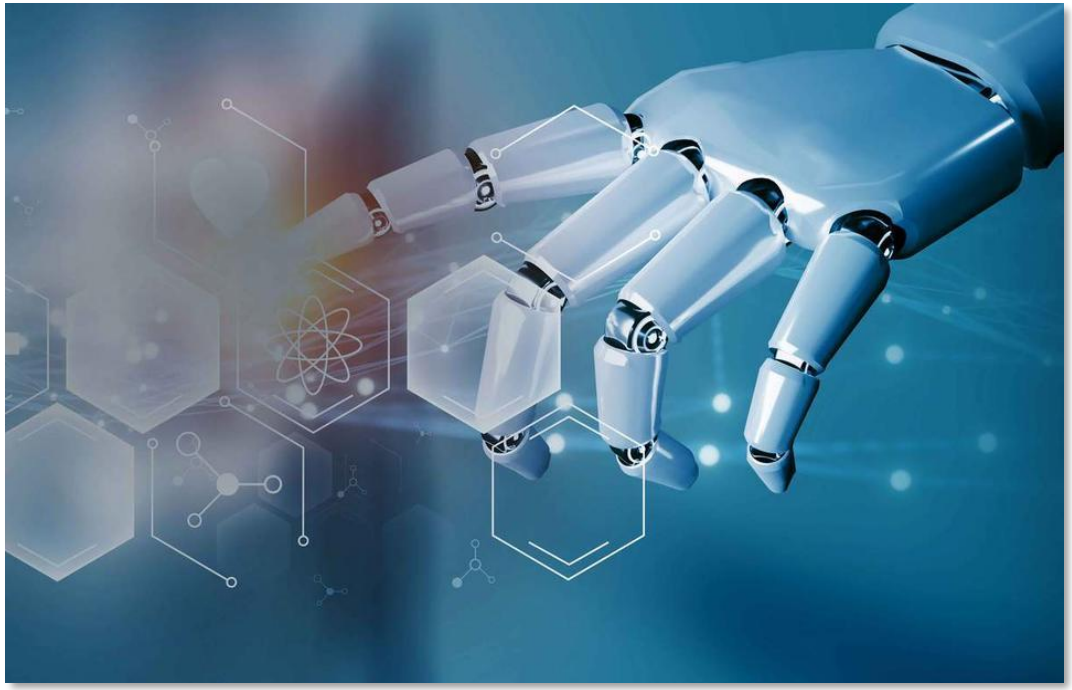
USG NSSCET Overview

- **Greater Investment in Pre-Standardization Research**
- Increase R&D funding for CETs
- Support development of standards that address risk, security, and resilience
- **Participation in Standards Development**
- Remove and prevent barriers to private sector participation
- Improve communication between public and private sector
- Enhance USG representation and influence in international standards governance and leadership
- **Workforce Development**
- **Ensuring Integrity in Standards Development**
- Deepen standards cooperation with partners and allies
- Facilitate broad representation in standards development

- **View the Strategy:** www.nist.gov/standardsgov/usg-nss



Implementation Planning: Stakeholder Input



The U.S. Government National Standards Strategy for Critical and Emerging Technology (USG NSSCET) was released in May 2023

Published a request for Information (RFI)

- Input on how to best implement the Strategy
- Input on investment, participation, workforce, and integrity, and inclusivity
- Responses submitted by December 22, 2023

Held listening sessions and stakeholder engagements

- 100+ events

Established a Subcommittee on U.S. International Standards Development Activity

- Under the NIST Visiting Committee on Advanced Technology

Key Findings: RFI and Listening Sessions

Public-private sector coordination

- work effectively in consortia and communities of practice
- develop and promote adoption of sector-specific standards including those critical to national security, public safety, security, health and environmental health and resilience

Federal Government coordination

- coordinate pre-standardization R&D investments
- coordinate activities, proposals, leadership opportunities, and engagement
- support the integrity of the international standards system
- promote WTO TBT Committee principles

Foreign government coordination

- work with likeminded partners and allies to ensure CET standards are developed to support U.S. interests
- advocate for a commitment to free and fair market competition
- advance trade policy and agreements that are technology neutrality and promote technology adoption

Standards funding opportunities

- target academia and small- and medium-sized enterprises (SMEs)

Key Findings: RFI and Listening Sessions - cont

Standards education

- enhance educational efforts and leverage academia as a critical partner to increasing U.S. engagement and training the next generation of standards professionals
- renew a commitment by academia to teaching the value and use of standards in a range of career fields

Standards communications

- explain the role of U.S. government and academia in our system
- provide education and awareness for senior leaders in industry, government, and academia
- understand the value of our system with regards to competitiveness and innovation in a range of career fields
- engage a wide range of market participants in standards efforts
- engage Congress to bolster support for R&D in CET and increase investment in pre-standardization research

Real and perceived barriers

- reduce visa wait times
- identify and eliminate knowledge gaps between U.S. policymakers and technical program leaders
- enhance government participation where government is the member (e.g., ITU)
- facilitate engagement by providing standards information, education, and to raise awareness among underrepresented stakeholders

Pathway to standards information

The Standards Information Center provides a gateway to navigating the dynamic U.S. and international standards landscape

The USA Enquiry Point for the World Trade Organization (WTO)

www.Standards.gov

Session 4:
Future State of Information Sharing to Enable Standards Development

Moderator

Muhammad Ali
Senior Standards Strategy and Policy Leader
HP, Inc.

Future State of Information Sharing Discussion

- What communication standards challenges does this sector face? What could be done to improve it?
- During the pre-standardization phases of technology, it is important to begin educating about the value and benefits of standards. How can we amplify this messaging to ensure it reaches the appropriate stakeholders?
- During the standards development phases, it is important to get the right information in front of the broadest group of stakeholders. How can stakeholders best socialize the standards development activity to get diverse and targeted stakeholders?
- During the implementation phases, can we increase the adoption of a standard once published? Think about this from a market adoption, regulatory acceptance, and/or conformity assessment standpoint.
- What information is critical to support effective bilateral communications between the public and private sector?

Future State of Information Sharing

Join at
slido.com
#2153 296
Passcode: PPPs4AI

What communication standards challenges does this sector face? What could be done to improve it? (Slido)

Challenges Communicated During Preregistration

- Several organizations addressing AI
- Different organizations have different goals & scales of efforts
- Space is evolving rapidly
- AI conversation is “noisy” & information gets diluted
- Protectionist approaches leading to decreased sharing
- No central repository of information.
- Varying terminology & definitions on AI concepts and standards
- Government(s) developing their own standards instead of collaborating with standards groups
- Government not disclosing use of AI
- Startups lack resources, networks, experience w/SDOs, and/or voice in the process in contrary to larger org’s

Future State of Information Sharing Discussion

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What is next?

Automated & Connected Infrastructure Session

- July 30th, 2024
- University of Michigan-Dearborn
- Focus on Transportation
  - Ground Vehicles
  - Aircraft

SD-PPP Use Case Development

- Literature Review
- Complete Interviews
- August 1st - August 15th use-case review
- Interested parties can submit a use-case to ANSI using template

ANSI to Develop Report

- Issue findings, general considerations, and best practices
- Targeted end of August
- Publicly available in September

Thank you!

Moderators and Presenters

- Laura Lindsey, Microsoft
- Clare Allocca, NIST
- Shawn Forrest, FDA
- Franck Journoud, NAM
- Natalia Globus-Martin, NIST
- Rohit Israni, CertientAI
- Kerri Haresign, CTA
- Mary Saunders, ANSI
- Amanda Benedict, AAMI
- Muhammad Ali, HP Inc.

Attendees and AAMI

- Attendees who completed the pre-registration questions
- Participants throughout today
- AAMI for hosting us
- AAMI staff for their hospitality

ANSI Project Team

- Rachel Hawthrone
- Sarah Katz
- Michelle Deane
- Sally Seitz

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AI & Machine Learning Brainstorming Session | July 17, 2024

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